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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,108	09/29/2000	Lynn Joens	M0-4890	2035

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AKZO NOBEL PHARMA PATENT DEPARTMENT
29160 INTERVET LANE
MILLSBORO, DE 19966

EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/677,108	JOENS, LYNN	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 May 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *21 May 2004*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

(a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: *see attached*.

3.☒ Applicant's reply has overcome the following rejection(s): see attached.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *None*.

Claim(s) objected to: _____.

Claim(s) rejected: *3-5,27,28 and 31*.

Claim(s) withdrawn from consideration: _____.

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

ADVISORY ACTION

An appeal under 37 CFR 1.191 was filed in this application on 5-21-04. Appellant's brief must be filed within the time period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.192(d)), to avoid dismissal of the appeal.

The amendment filed 5-21-2004 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because:

The proposed amendment raises new issues that would require further consideration and/or search. Specifically, the proposed amendments raise issues under 35 U.S.C 112, first and second paragraphs as well 35 U.S.C. 103(a).

All the rejections are maintained for reasons of record. Applicant's arguments are predicated, in part, on the non-entered amendment. Applicant's arguments, to the extent they read on the pending claims are addressed below.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 3-5 and 27-29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Knittel et al. (WO 96/369629 – IDS-14) in view of Joens et al (U.S. Patent 5,610,059 - IDS-4) is maintained for reasons of record.

Applicant argues:

1. The conclusion that the discussion by Joens et al. of developing a bacterin using known techniques and administering it to pigs to permit them to mount an effective immune response provides a reasonable expectation of success is wrong.

2. There is no disclosure by Joens et al. regarding the actual production or use of a vaccine.

3. Joens et al. is limited to the isolation, characterization and production of the strain deposited as ATCC No. 55370 (note that it is assumed that Applicant's recitation of the ATTC No. as 55730 was an inadvertent typographical error).

4. Nothing more than conventional methods for producing a vaccine are discussed in the hypothetical.

5. In view of the lack of predictability in the vaccine art, the disclosure of Joens et al. provides nothing more than a suggestion to make a vaccine by conventional methods.

6. Knittel et al. disclose *L. intracellularis* vaccines using both attenuated and killed L. *intracellularis*.

7. The success of one strain of as a vaccine does not predict success with any other.

8. With the present amendments, the instant invention includes the limitations whereby the *L. intracellularis* antigen component consists essentially of the strain deposited as ATCC No. 55370 that on administration to swine induces the production of antibodies to specific antigens

that were identified by Western blot. The claims are now limited to immunogenic compositions in which the *L. intracellularis* must be the specific tissue culture produced, whole cell *L. intracellularis* deposited as ATCC deposit No. 55370.

9. Even with Knittel et al. before him and the 55370 in hand the ordinary practitioner would have to formulate a vaccine, test it and possibly attempt to formulate a vaccine providing protection against heterologous challenge. Hence a successful result could not be predicted with assurance.

Applicant's arguments have been fully considered and deemed non-responsive.

With the exception of claim 31, the rejected claims are drawn to a an **immunogenic composition** comprising **inactivated *L. intracellularis*** strain deposited as ATCC deposit No. 55370 and optionally an **adjuvant** or an **inactivating agent.** Only claim 31 reads on vaccines since it is drawn to a method of using said immunogenic composition to protect a mammal from the disease caused by *L. intracellularis*. Moreover, the *L. intracellularis* can be in the form of a whole cell or a whole cell lysate. It should be noted that the elected invention is **limited to whole cell culture** vaccines (immunogenic compositions).

In response to Points 1-7 and 9 as they pertain to claims 3-5 and 27-28, it is noted that the features upon which applicant relies (i.e., that the claimed compositions are vaccines) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regard to point 8, said arguments are predicated on amendments not made of record and hence are not persuasive.

With regard to Points 1-7 and 9 as they pertain to claim 31, the ability to induce protective antibodies is an inherent property of the microorganism (vaccine composition) since cell preparations would comprise all the antigens of the *L. intracellularis.*

As outlined previously, Knittel et al. disclose vaccine compositions comprising inactivated whole cell *L. intracellularis* or lysates thereof and an adjuvant (see page 17-18 and Example 6) and the use of said vaccines in swine. Knittel further disclose that said bacteria can be inactivated by the addition of formalin (see page 17, lines 30-33) and that the adjuvant used could be aluminum hydroxide (see page 18, lines 1-4). Knittel et al. differ from the instant invention in that they don't explicitly disclose the use the organism with the ATCC deposit No. 55370. Joens et al. disclose methods of propagating *L. intracellularis* in Henle 407 cells. The isolated *L. intracellularis* is further disclosed to be inoculated into porcines in order to check its pathogenicity (see examples 1 and 2). Moreover, the isolated *L. intracellularis* disclosed by Joens et al. was deposited with ATCC with the deposit number 55370 (see column 8, lines 14-21 and claim 1). Additionally, Joens et al. disclose that said the *L. intracellularis* culture could be used to develop a "bacterin" using techniques known in the art such as heat treatment or chemical inactivation (see column 4, lines 6-16) said bacterin could be administered to porcines to "permit the pigs to mount an effective immune response against the agent (PPE)". Therefore it would have been obvious to one of skill in the art to use the antigen disclosed by Joens et al. (ATCC deposit No. 55730) in the vaccine compositions of Knittel et al. Moreover, it would have been equally obvious to use the resulting vaccine compositions to protect swine from diseases caused by *L. intracellularis* infection. Contrary to Applicant's assertion, the disclosure by Joens et al. that said bacterin (immunogen) could be administered to pigs to "permit the pigs to mount an effective

immune response against the agent (PPE) would provide one of skill in the art not only of a reasonable expectation of success but a motivation to use the disclosed antigen (ATCC No. 55730) as a vaccine. Moreover, it is not necessary for the skilled to be assured of success, he merely has to have a reasonable expectation of success. Therefore, for the reasons set forth above, the combination of the disclosures by Knittel et al. and Joens et al. renders all the rejected claims obvious.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 28 under 35 U.S.C. 112, second paragraph, for having insufficient antecedent basis for the limitation "*L. intracellularis* antigen" in line 3 is maintained for reasons of record. Applicant's arguments have been fully considered and deemed non-persuasive since they are predicated on amendments not made of record.

The rejection of claim 29 under 35 U.S.C. 112, second paragraph, for having insufficient antecedent basis for the limitation "*L. intracellularis* antigen" in line 3 is maintained for reasons of record. Applicant's arguments have been fully considered and deemed non-persuasive since they are predicated on amendments not made of record.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICIA A. DUFFY
PRIMARY EXAMINER

Robert A. Zeman
June 24, 2004